DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 14 1997

TO: Manufacturers and Importers of Television Products

SUBJECT: Exclusion from the Radiation Performance Standard (21 CFR 1020.10) for Camcorder Viewfinders

ISSUE

The Consumer Electronics Manufacturers Association has requested that the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), exempt low voltage television products, especially camcorder viewfinders, from the Performance Standard for Televisions Receivers, 21 CFR 1020.10.

BACKGROUND

Electronic products distributed in U.S. commerce are required to meet applicable radiation safety performance standards promulgated under Section 534 of the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act (the Radiation Control for Health and Safety Act of 1968). Manufacturers must certify each product to be in compliance with applicable standards.

On March 7, 1996, the Consumer Electronics Manufacturers Association (CEMA), a sector of the Electronic Industries Association, requested that television products operating at less than 5 kilovolts (kV) be exempt from the standard, 21 CFR 1020.10. CEMA asks that these low voltage products, especially camcorder viewfinders, be exempt because there is little likelihood of producing or emitting x rays. The change is expected to reduce the regulatory burden on industry, with negligible impact on public health.

The CDRH recognizes that the likelihood of x-ray production from low voltage products is small. An exclusion from the performance standard is appropriate for camcorder viewfinders since there is sufficient information on the product technology to confirm the unlikely production of radiation from such products. However, in the absence of data regarding new technologies, failure modes, and voltage levels under worst-case conditions, additional exclusions should be limited at this time.

GUIDANCE

CDRH considers the Performance Standard for Television Receivers (21 CFR 1020.10) not applicable to camcorder viewfinders; therefore they are not subject to requirements for certification (21 CFR 1010.10(a)), identification (21 CFR 1010.10(b)), and importation declaration (21 CFR 1005 and Form FDA 2877) under the following conditions:

1. The camcorder viewfinders must not operate at voltages greater than 5 kilovolts (kV) under any conditions of component failure.

2. Manufacturers must document conformance with the first condition in the abbreviated report on the chassis family (21 CFR 1002.12). Any suspect accidental radiation occurrences must be reported in accordance with 21 CFR 1002.20.

In accordance with FDA's Good Guidance Practices, comments are invited. This guidance document represents the agency's current thinking on the applicability of the television performance standard to camcorder viewfinders. It does not create or confer any right for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and/or regulations.

Any comments or questions should be directed to the Electronic Products Branch at the address above, by telephone at 301-594-4654 or by facsimile at 301-594-4672.

Sincerely yours,

Lillian J. Gill

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 31 1984

TO: ALL MANUFACTURERS AND IMPORTERS OF TELEVISION RECEIVERS

SUBJECT: Application of the Federal Performance Standard for Television Receivers to Television Products Using a Liquid Crystal Display

Background:

Extremely small television products using liquid crystal displays have recently been developed. Since these products do not incorporate any form of high voltage vacuum tube or cathode ray tube, they are inherently incapable of generating x radiation. Because of this, the National Center for Devices and Radiological Health has been asked if these devices are subject, or should be subject to the Federal performance standard for television receivers, 21 CFR 1020.10.

Discussion:

A television product using a liquid crystal display meets the definition of television receiver in 21 CFR 1020.10(b)(4) in that it is "an electronic product designed to receive and display a television picture through broadcast, cable, or closed circuit television." However, the television receiver standard was intended to control x radiation emission from products incorporating CRT's and other high voltage vacuum tubes which have the capability of generating x rays. A product which does not incorporate such components is inherently incapable of producing or emitting that form of radiation addressed by the standard. Therefore, it meets the x radiation emission limits of the standard by definition. Application of the standard to such products would not serve a useful purpose while imposing unnecessary burdens on the manufacturer, e.g., application of certification and identification labels, x radiation testing, and reporting and recordkeeping.

Policy:

It is the position of the National Center for Devices and Radiological Health that television receivers using liquid crystal displays and containing no high voltage vacuum tubes or other components which can generate x radiation, are not subject to the Federal performance standard for television receivers (21 CFR 1020.10).

1/31/84

John C. Villforth
Director
National Center for Devices
and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 14 1997

TO: Manufacturers and Importers of Television Products

SUBJECT: Changes to TV Annual Reports (21 CFR 1002.13)

ISSUE

The Consumer Electronics Manufacturers Association (CEMA), a sector of the Electronic Industries Association, has requested that the Food and Drug Administration(FDA), Center for Devices and Radiological Health (CDRH), modify the annual report guide for television products.

BACKGROUND

Manufacturers of electronic products are required to submit radiation safety reports under Section 537(b) of the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act (the Radiation Control for Health and Safety Act of 1968). Information submitted must conform to CDRH guides or instructions when they exist (21 CFR 1002.7). The latest reporting guide for television products is dated October 1995.

By letter dated May 9, 1996, CEMA asked that information on testing of television products be summarized by plant and chassis family rather than by individual model as currently requested. The change is expected to reduce tracking resources and paperwork burden on industry, without impact on FDA or public health.

GUIDANCE

CDRH concurs with the CEMA suggestion and is revising the reporting guide for television products accordingly. Revised tables and questions for sections 7.5, 7.6, and 7.7 are enclosed. They may be used now for preparing new annual reports.

In accordance with FDA's Good Guidance Practices, comments are invited. This guidance document represents the agency's current thinking on annual reporting of television products. It does not create or confer any right for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and/or regulations.

Any comments or questions should be directed to the Electronic Products Branch at the address above, by telephone at 301-594-4654 or by facsimile at 301-594-4672.

Sincerely yours,

Lillian J. Gill

Lillian J Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure

Changes to Annual Reporting Guide for Television Products
(7.5 Current Production & 7.6 Test Results to be combined)

7.5 Current Production and Test Results - new table

By Factory:

Product Report Accession Number	Chassis Family	Quantity Produced	Number Tested	Maximum Radiation	Number of sets/lots Rejected

7.6 Model/Brand listing - new table

By Factory:

Accession No. or Chassis Family	Model No.	Brand	Product Type *	Screen Size

* = M (monitor); P (projector); R (receiver);
V (viewfinder); O (other, specify)

7.7 Life Testing - revised questions:

7.7.1 How many sets were life tested?
7.7.2 Were there any life test failures?
If so, specify which chassis was involved, what the failure was, and the corrective actions taken.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 24 1992

TO: ALL MANUFACTURERS AND IMPORTERS OF TELEVISION PRODUCTS
ALL FDA FIELD OFFICES

SUBJECT: Clarification of Import Requirements for Television Products Which Are Intended for Use in Countries Other Than The United States (Import-for-Export)

On November 7, 1991, the Center for Devices and Radiological Health, Food and Drug Administration (FDA) announced the exemption from certification requirements for certain imported television products was being canceled effective February 7, 1992. That announcement resulted in a number of questions which indicate some fundamental misunderstandings about the entire import process. The purpose of this memorandum is to summarize the import requirements and clarify the applicability of requirements and policies related to television products.

The basic procedure for importing electronic products subject to FDA performance standards is described in the May 28, 1981, memo to all foreign manufacturers and importers. In summary, all entries must be filed with the local FDA District Office on Form FDA 701 entitled "Importers Entry Notice" and, if the product is subject to radiation safety performance standards, a Form FDA 2877 entitled "Declaration for Products Subject to Radiation Control Standards".

In the mid 1980's, FDA exempted certain television products from the performance standard which could not be used in the United States and were imported for the purpose of export. Some very basic criteria were established which, if met, negated the need to certify the products and to file the Form FDA 2877 at the time of import. If that criteria was not met, then the normal import procedures must be followed. Widespread abuse by importers of broadcast television receivers led to the November 7, 1991, cancellation of the exemption. Television products intended for use as broadcast receivers must be certified and importers must follow the import procedures specified in the May 28, 1981, notice. A properly completed Form FDA 2877 must be filed at the time of import.

It has been brought to FDA's attention that although the November 7 notice was intended for broadcast television receivers, it unduly restricts importation of certain video display devices intended as components in other products which in turn are exported, e.g. computer systems. The FDA acknowledges that strict enforcement of the policy change will represent undue hardship on that segment of the industry. Therefore, FDA will continue to exempt imported television products from the performance standard and the certification requirements provided they comply with the following criteria.

Criteria for Exemption from Television Product Performance Standard

1. Products are not intended to receive and/or display broadcast signals and are declared as intended for export on FCC Form 740 (or its electronic equivalent) in accordance with the Federal Communication Commission (FCC) rules 47 CFR Part 2. The FCC declaration shall be attached to Form FDA 701.

The Federal Communications Commission (FCC) specifies certain import conditions for radiofrequency devices (including television products and microwave ovens) (47 CFR 2.1204). One condition is that the radiofrequency device be imported solely for export and will not be marketed or offered for sale for use in the United States (47 CFR 2.1204(a)(5)). As defined in the FCC rules, marketed means sell or lease or offer for sale or lease (including advertising for sale or lease or display at a trade show) or import, ship, or distribute for the purpose of selling or leasing or offering for sale or lease.

2. Alternatively, products meet all of the following criteria:

   a. The products are not intended to receive and/or display broadcast signals and are designed to operate only on power supplies in the range of 210-250V/50Hz.

   b. Records of disposition of the products shall be maintained by the importer for a period of 5 years and shall be provided to FDA upon request.

   c. Attached to Form FDA 701 is an affirmation that all imported receivers comply with all criteria for exemption and that product will be properly labeled and will be exported and not introduced into commerce in the United States. A sample affirmation statement is attached.

Electronic products for which exemption from performance standards is granted in accordance with this policy, and its shipping container, shall be labelled for export in accordance with 21 CFR 1010.20.

Persons having questions or desiring further information should contact the Television, Acoustic and Microwave Products Branch HFZ-313, Center for Devices and Radiological Health, 1390 Piccard Drive, Rockville, Maryland 20850, telephone (301) 427-1161.

Edwin A. Miller

Edwin A. Miller, Director
Division of Standards Enforcement
Office of Compliance and
Surveillance
Center for Devices and
Radiological Health

SAMPLE AFFIRMATION

DATE: _____

ENTRY NUMBER: _____

MANUFACTURER: _____

MODELS/ BRANDS: _____

I, as the responsible person for the importing firm listed below, affirm that the television products in this entry are not intended to receive or display broadcast signals and operate on only power supplies for 210-250 volts/ 50 hertz. These products have been (or will be) properly labeled for export only and will not be introduced into U.S. commerce. Records showing the disposition of these products will be maintained for five years and shall be provided to a duly authorized Food and Drug Administration (FDA) official upon request. I am aware that falsification of information to the FDA is a violation of Title 18 of the U.S. Code, and may be subject to criminal prosecution.

Signature: _____

Name (print): _____

Title: _____

Importer: _____

Address: _____
(include zip code) _____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

NOV 7 1991

TO: ALL MANUFACTURERS AND IMPORTERS OF
TELEVISION PRODUCTS
ALL FDA FIELD OFFICES

SUBJECT: Cancellation of Exemption for Television Receivers which are Intended for Use in Countries Other Than the United States (Import-for-Export)

BACKGROUND:

In the past, many television models manufactured for the international market were incapable of successful operation in the United States. Television receivers intended for use in other countries utilized broadcast systems as well as power line voltages and frequencies not encountered within the United States.

Under those conditions, importers have been allowed to import uncertified television receivers for export purposes, provided that certain specific criteria for exemption from the DHHS (Department of Health and Human Services) television performance standard were met in accordance with the Food and Drug Administration's (FDA's) Compliance Program 7382.007A. (See attached Notice dated November 7, 1985.)

However, modern designs now make operation of multisystem television receivers possible in virtually any country in the world, including in the United States. The technical basis for exemption no longer exists.

At the present time, uncertified multisystem television products are finding their way into the United States market illegally. These products should have the same degree of inherent radiation safety as that afforded by the Federal Performance Standard for Television Products (21 CFR 1020.10).

POLICY:

The attached November 7, 1985, notice is canceled. Effective February 7, 1992, all television receivers imported into the U.S. that use cathode ray tube displays, including so called "multisystem" televisions and those designed or intended for the export market, must be in full compliance with Federal regulations.

FDA district personnel and the United States Customs Service will be inspecting import-for-export television products for compliance with the Federal Performance Standard for Television Products (21 CFR 1020.10) to ensure that they have been properly certified and comply with all applicable requirements.

The products must bear a certification statement which is the manufacturer's declaration that the product has been tested and found to be in compliance with the Federal regulations. Reports describing the product and the basis for certification (compliance testing program) must be filed with the FDA's Center for Devices and Radiological Health (CDRH) in accordance with 21 CFR 1002. Television products that do not comply with the standard or for which the required report is not on file at CDRH will be denied entry.

Merchandise refused admission shall be destroyed or returned to the country of origin unless a timely and adequate petition for permission to bring the product into compliance with the standard is filed and granted under 21 CFR Parts 1005.21 and 1005.22.

Persons having questions or desiring further information should contact the Television, Acoustic and Microwave Products Branch HFZ-313, Center for Devices and Radiological Health, 1390 Piccard Drive, Rockville, Maryland 20850, telephone (301) 427-1161.

Sincerely yours,

Edwin A. Miller

Edwin A. Miller, Director
Division of Standards Enforcement
Office of Compliance
and Surveillance
Center for Devices and
Radiological Health

Enclosure: November 7, 1985, Industry Notice

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

NOV 7 1985

CANCELLED

TO: All Manufacturers and Importers of Television Products

SUBJECT: Importation of Non-Compliant Television Receivers Which Are Intended for Use in Countries Other Than the United States

Importers have been allowed to import noncertified CCIR Standard 220 volt television receivers for exportation purposes provided that certain specific criteria for exemption from the television performance standard were met in accordance with Compliance Program 7382.007A. These receivers were sold to United States (U.S.) distributors who, in turn, supposedly sold them to consumers who were either traveling or relocating overseas. Since these receivers were not originally designed to receive television signals from within the U.S. or operate on standard 60 Hz, 110-120 VAC power sources unless extensive reconditioning was done, permitting these sets to enter the U.S. without certification, did not pose a hazard to the public health.

Due to recent changes in the technology of the television industry, some, if not all, receivers designed for the CCIR broadcast standard are now also designed to be, and are capable of, operation within the U.S. Such receivers are considered to be subject to the Federal Performance Standard for Television Receivers (21 CFR 1020.10) and must be certified before admission into the U.S.

Some manufacturers already test and certify their multi-system television receivers in accordance with the U.S. television standard. These products may be imported into the U.S. claiming Affirmation B on Form FD 2877. They should not be labeled for export only. Other manufacturers have chosen not to certify these products for U.S. use. These manufacturers should notify their customers that these products may not be imported into the U.S., and they should not ship such products to U.S. addressees.

FDA District personnel and the U.S. Customs Service have been notified that all television receivers which are capable of operation in the U.S. (i.e., they will accept NTSC 3.58 broadcast signal and will operate on 60 Hz 110-120 VAC) may not be imported and are to be detained unless they are certified by the manufacturer to comply with the Performance Standard for Television Receivers.

Television receivers which cannot be operated in the U.S. may continue to be imported for export only (in accordance with CP 7382.007A) (see enclosure) if they are properly labeled and meet the requirements of the country to which they are intended for export.

Nothing in this notification shall be construed as altering the Center's policy regarding monitors, display units, or other television products.

Edwin A. Miller

Edwin A. Miller, Director
Division of Radiological Products
Office of Compliance
Center for Devices
and Radiological Health

CANCELLED

PART III - INSPECTIONAL

1. Operations

A. Import Activities

1. Exemption Criteria

Importers are permitted to import noncertified CCIR Standard 220 volt television receivers for exportation purposes and noncertified television receivers and microwave ovens for testing/evaluation purposes when specific criteria for exemption from the appropriate performance standard have been met.

a. Noncertified CCIR television receivers are excluded from the performance standard as prescribed in Section 358(a)(3) of the Radiation Control for Health and Safety Act if:

- The foreign manufacturer affixes a label or tag to each shipping container which states

  "WARNING-CCIR TELEVISION RECEIVER FOR EXPORT ONLY/NOT INTENDED FOR USE IN THE UNITED STATES. THIS TELEVISION RECEIVER HAS NOT BEEN TESTED FOR COMPLIANCE WITH THE U.S. FEDERAL PERFORMANCE STANDARD FOR TELEVISION RECEIVERS."

- The TV receiver has one label permanently affixed to the receiver's exterior (excluding the bottom) and a "stick on" temporary label affixed to the center of the TV screen.

- The importer (on or prior to date of entry) provides FDA with a statement that all imported receivers bear the required labeling for exemption and meet all the applicable requirements of the country to which the product is to be exported.

The TV receivers for which this Program Circular are directed are CCIR Standard TV Receivers. These receivers do not meet the U.S. Federal performance standard; operate only with a 220 volt power source; do not receive the standard U.S. broadcast signal and are generally inoperable in this country without major modifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 14 1997

TO: Manufacturers and Importers of Consumer Electronic Products

SUBJECT: Date of Manufacture Label for Electronic Products Subject to Radiation Standards

ISSUE

The Consumer Electronics Manufacturers Association has requested that the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), exempt manufacturers of electronic products from the required label providing the date of manufacture or to permit date coding.

BACKGROUND

Manufacturers of electronic products are required to comply with radiation performance standards promulgated under Section 534(a)(1) of the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act (the Radiation Control for Health and Safety Act of 1968). The regulations, 21 CFR 1010.3, specify that an identification label or tag must be affixed to each product with the date of manufacture.

On March 7, 1996, the Consumer Electronics Manufacturers Association (CEMA), a sector of the Electronic Industries Association, requested a change in the date format specified in the regulations and then subsequently questioned the need for providing a date on the label at all. The original intent of the label was to identify which products are subject to a standard (as opposed to ones manufactured prior to the effective date) and to identify products subject to differing requirements when the performance standards are amended. Since the television and microwave oven standards have not been amended since 1983 and the laser standard is seldom amended in any manner that affects the consumer product industries, CEMA asks that the requirement for the label be exempted until any future amendments to these standards are promulgated. The change is expected to reduce the tracking resources and paperwork burden on industry, with negligible impact on FDA or public health.

GUIDANCE

The CDRH concurs that there is little need for the date of manufacture on the identification label at this time and failing to provide the information does not impact public health. As permitted by Section 539(d) of the Act, the CDRH

will not object to manufacturers omitting the date of manufacture from the identification label required by 21 CFR 1010.3 from consumer (non-medical) electronic products under the following conditions:

1. Each product is marked with a serial number or other identification by which the manufacturer may identify the date of manufacture in case of any regulatory action or investigation.

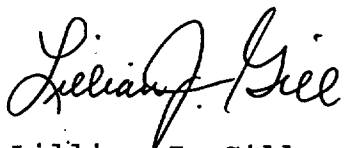
2. The date of manufacture is included on the label within 30 days after a final rule to amend an applicable standard is published in the Federal Register, if the amendment adds or amends (not reduces or eliminates) any aspect of performance to which that electronic product must comply.

Failure to comply with an applicable standard is a violation of Section 538(a)(1) of the Act. Violations will result in disallowing this guidance by the responsible parties and are subject to civil penalties not to exceed $1000 per violation and $300,000 maximum. Providing false information to the U.S. government is a violation of the U.S. Code, Title 18, and subject to criminal prosecution.

In accordance with FDA's Good Guidance Practices, comments are invited. This guidance document represents the agency's current thinking on date of manufacture labeling on consumer electronic products. It does not create or confer any right for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and/or regulations.

Any comments or questions should be directed to the Electronic Products Branch at the address above, by telephone at 301-594-4654 or by facsimile at 301-594-4672.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 14 1997

TO: Manufacturers and Importers of Consumer Electronic Products

SUBJECT: Importation of Radiation-Emitting Electronic Products for Investigation and Evaluation During Design Development

ISSUE

The Consumer Electronics Manufacturers Association has requested that the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), expand the exemption for consumer products imported for the purpose of test and evaluation during design and production development.

BACKGROUND

Section 536(a) of the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act (the Radiation Control for Health and Safety Act of 1968) requires that all imported electronic products, for which applicable radiation performance standards exist, shall comply with the standards and shall bear certification of such compliance. Before the products can be permitted to enter the U.S., importers are required to submit with each shipment certain import entry papers through the District Director, U.S. Customs Service, to the appropriate FDA district office.

Exemption from certification of electronic products for the purpose of research, investigations, studies, demonstrations, or training is permitted by Section 538(b) of the Act. Current policy permits FDA district offices to grant such exemptions for individual entries, usually for 180 days, while the products remain in import detention status. Importers must make a written declaration to FDA (Form FDA 2877, "Affirmation C") and execute a bond with the U.S. Customs Service. Liquidation of the Customs bond is attained only through exportation or destruction of the products.

By letters dated May 17, 1982; August 25, 1983; and May 22, 1987, CDRH exempted up to 10 units of the following products from the applicable performance standard when they are intended for investigations: television products, microwave ovens, and laser products that do not exceed the limits of Class I during any conditions of operation, maintenance, or service (hereafter referred to as inherent Class I laser products). The products are not subject to certification requirements or the Customs bonding process under certain conditions. These products are generally used for acceptance testing (FCC, UL, etc.), establishment of production line procedures, and applications evaluation. While they may be fully operational, they may not be the final design and have not received final acceptance testing.

On March 7, 1996, the Consumer Electronics Manufacturers Association (CEMA), a sector of the Electronic Industries Association, requested a change to the industry-wide investigations and evaluation exemption. CEMA asks that the number of units to which the exemption applies be increased to 50 units for TV products and Class I laser products and to 200 units for CD-ROM and new DVD (digital versatile disc) laser products, to reduce unnecessary costs to manufacturers in both time and money. Increase to 50 units will accommodate the industry need for establishing production processes. Increase to 200 units for CD-ROMs and DVDs will accommodate the need for software evaluation and development. Because there will be no commercial distribution of the products, the change is expected to reduce the tracking and paperwork burden on industry, FDA, and U.S. Customs, without impact on public health.

EXEMPTION

Under the authority of Section 538(b) of the Act, exemption from certification to the applicable radiation performance standards and the execution of a Customs bond is granted for consumer electronic products imported into the U.S. for investigations and evaluation during the design and production development phase with the following conditions:

1. The quantity of products in any single import entry of television products, microwave ovens, and inherent Class I laser products can not exceed 50 units; except other laser products requiring software to operate, such as CD-ROMs and DVDs, are limited to 200 units.

2. Each product and its shipping carton must bear a label stating: "TESTING/EVALUATION ELECTRONIC PRODUCT - NOT TO BE SOLD IN THE UNITED STATES. THIS PRODUCT HAS NOT BEEN TESTED FOR COMPLIANCE WITH THE APPLICABLE U.S. RADIATION PERFORMANCE STANDARD."

3. The importer or consignee must establish written procedures for maintaining control and final disposition of the products.

4. Form FDA 2877 (Declaration For Electronic Products Subject to Radiation Performance Standards), or the equivalent electronic filing, must be submitted to the FDA district office before the shipment arrives. Until the Form 2877 is revised to provide an affirmation for this exemption, mark Affirmation A and write: "These products meet the CDRH Exemption For Product Development and will not be commercially distributed at any time."

5. Shipments in excess of the quantities specified in item 1, or otherwise not meeting the conditions above, shall be placed in import detention status.

Movement of uncertified products in U.S. commerce is a violation of Section 538(a)(1) of the Act. Violations will result in voiding this exemption for the responsible parties and are subject to civil penalties not to exceed $1000 per violation and $300,000 maximum. Providing false information to the U.S. government is a violation of the U.S. Code, Title 18, and subject to criminal prosecution.

This exemption supersedes the previous exemptions dated May 17, 1982; August 25, 1983; and May 22, 1987.

Any questions regarding this exemption or any imports procedure should be directed to the imports officer at the FDA district office nearest the port of entry.

Sincerely yours,

Lillian J. Gill

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health